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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,421	04/09/2004	Peter Ospyka	32469-303686	1219

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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,421

Applicant(s)

OSP YKA, PETER

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 21-65 is/are pending in the application.
- 4a) Of the above claim(s) 23, 26-30 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 21, 22, 24, 25, 31-33, 35-40 and 43-50 is/are rejected.
- 7) ☒ Claim(s) 34, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/27/2006 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. The Objection to the drawings has been withdrawn since the limitation of a "loop structure" has been cancelled from the claims.

Claim Rejections - 35 USC § 112

3. The amendments to claims 37 and 41 to overcome the 35 USC 112(2) rejections are acknowledged and accepted. Therefore, the 35 USC 112(2) rejections of claims 37 and 41 have been withdrawn.

Response to Arguments

4. Applicant's arguments with respect to claims 18, 19, 21, 22, 24, 25, 31-40 and 42-50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18, 19, 21, 22, 24, 25, 31-33, 35-39, 43-48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Trabucco (US 4,378,023). Trabucco discloses an

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apparatus for inserting an electrode into the myocardium of the heart. The apparatus includes an anchor, which the Examiner considers to be the combination of core 2 and the pointed members 9,10. The core 2 contains an attachment area 15 formed of a receiving aperture that is disposed at a trailing end of the anchor (see figure 2). A 16 with a knob 17 is detachably coupled to the attachment area, which helps insert the pointed members of the anchor through the myocardium to an operating position when the tool is rotated (Col. 8, lines 61-65 and Col. 10, lines 35-44). Regarding the limitation of "a tension element attached to the anchor," either the tool 16 or the sleeve 19 can be considered a tension element, and both are shown to be attached to the core in figure 2.

7. Regarding claims 19 and 45, Trabucco discloses a receiver tube 22 for performing a canal through the myocardium, such that the tube holds both the anchor and the tool during insertion in the heart (see figures 4-8 and Col. 10, lines 6-36).

8. Regarding claim 22, the pointed member of the anchor are held within the core during insertion in the myocardium, and then they are expanded into an operating position (Col. 10, lines 34-44).

9. Regarding claim 24, the core 2 of the anchor is rod-shaped with a first end 4 and a second end 3, and the attachment area is a longitudinal opening in the first end for receiving the tool (see figure 2). Furthermore, if the tool is also considered the tension element, then figure 2 shows it extending into an area between the first and second end. Furthermore, if the sleeve is considered the tension element, then figure 2 also shows that the sleeve is connected to the core between the first and second ends.

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10. Regarding claim 25, the tension element 16 is shown in figure 2 to extend past the center of the anchor such that it is attached between the center of the anchor and the leading end.

11. Regarding claim 31, Trabucco discloses the tool to be a stylet, which is inherently thin and flexible (Col. 8, line 61).

12. Regarding claims 32, 33, 43, 46 and 50, Trabucco discloses an electrode 21 that defines an inner guide channel such that the tension element 16 is accommodated within. As shown in figure 2, the electrode 21 connects to the first end 4, creating an exit opening through which the tension element connects to the core 2. Trabucco further discloses that the core 2 is an electrically conducting material that acts as a pole for stimulating the myocardium, and as such, the tension element is attached to the electrode, and an end of the tension element will inherently be anchored within the myocardium along with the electrode (Col. 8, lines 43-45).

13. Regarding claim 35, the size of the attachment 15 acts as a fastening element for attaching the tension element to the electrode.

14. Regarding claims 36, 37 and 47, the tension element 16 has a knob 17 that appears to have a diameter which exceeds an inner diameter of the guide channel and is spaced away from the anchor (see figure 2). The knob is considered a "stop" since by turning the knob, the electrode is fixed "to prevent movement in either a forward or a rearward direction."

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15. Regarding claims 38 and 48, Trabucco discloses that two conductors could be connected to respective poles to create a bipolar electrical circuit with an anode and a cathode (Col. 11, lines 1-4).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey). Trabucco, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart. Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

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applicant's invention to modify the system of Trabucco by adding two electrodes extending from a common supply as taught by Wesbey in order to stimulate two locations of the heart at the same time.

Allowable Subject Matter

19. Claims 34, 41 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB